M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 8, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Chemistry Project Management in Support of the ANDA Approval Process

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

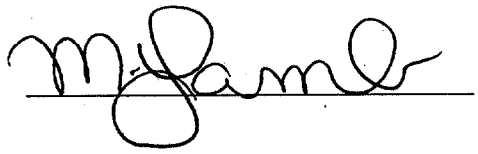
Title of Presentation: Chemistry Project Management in Support of the ANDA Approval Process

Presented for: 1999 Fall Technical Workshop

Date Presented: 10/18/99

Presented by: Mark Anderson, R.Ph.

Number of Pages: 15



Attachment

90S-0308

M650

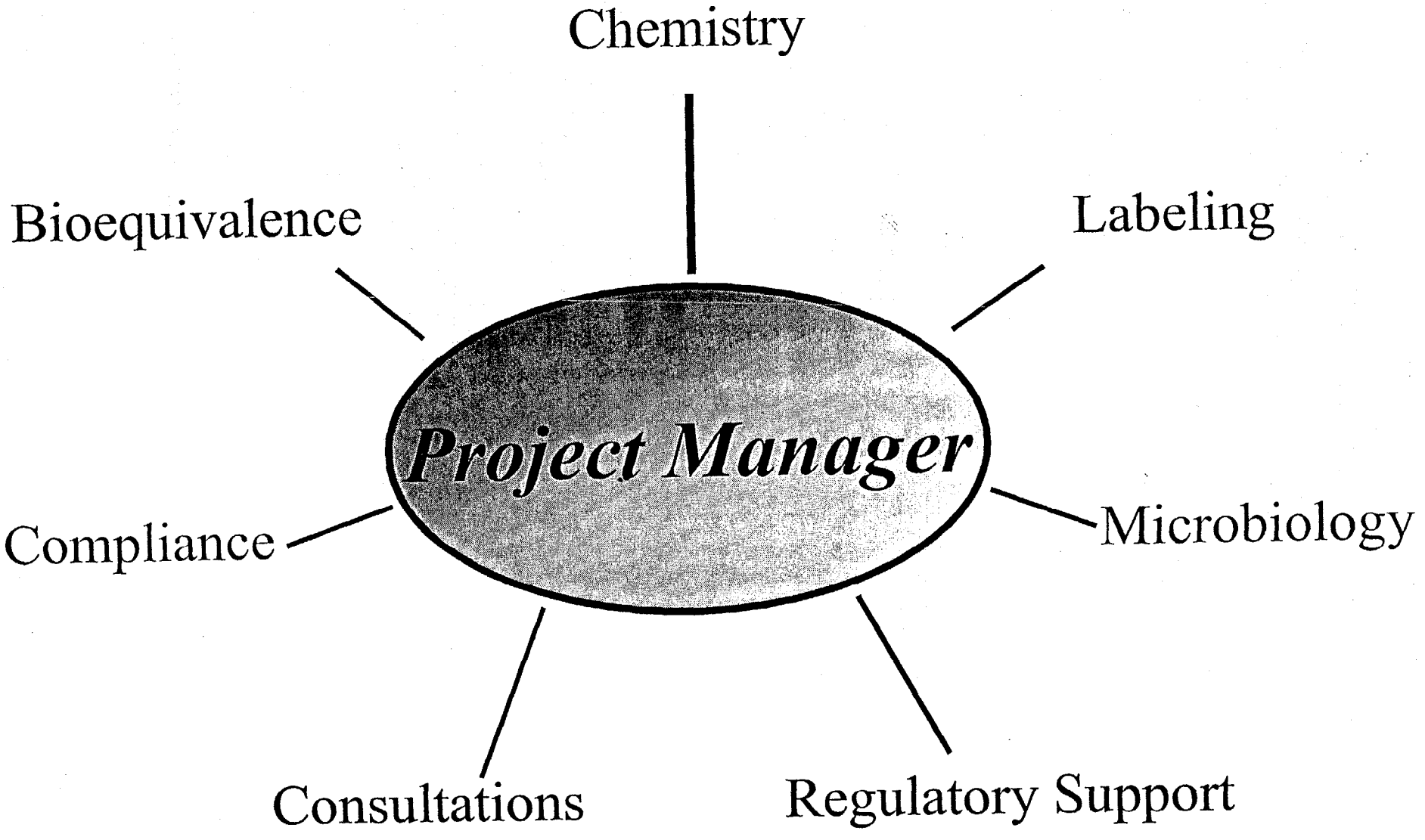
Chemistry Project Management in Support of the ANDA Approval Process

1999 Fall Technical Workshop
October 18, 1999

Mark Anderson, R.Ph.
Senior Project Manager
Office of Generic Drugs

Outline

- Chemistry Project Manager = ANDA Project Manager
- Point of contact for industry status calls
- Issues to consider regarding status calls
- Other types of calls to the Project Manager
- Facilitates the review process
- Provides consistency in the review process
- Role of the Project Manager in the final approval process
- Roles in processing supplemental applications


Chemistry
Bioequivalence
Labeling
Project Manager
Compliance
Microbiology
Consultations
Regulatory Support

Chemistry Project Managers: Roles and Responsibilities

- Serve as the primary point of contact for all status calls and other inquiries
- Important to contact the correct project manager
  - Refer to acceptance for filing letter
  - Refer to Chemistry Team/Therapeutic class information

Status Calls (MAPP 5020.1) (http://www.fda.gov/cder/mapp.htm)

- What to expect from a status call
  - Return calls within 48 hours
  - Time frames for completion are estimates
  - Not in position to discuss deficiencies or Major/Minor/Fax status while in draft
- Expectations OGD has from industry
  - Important not to call too frequently
  - Do not attempt to call multiple people about status

Other Types of calls to the Chemistry Project Manager

- Clarification of chemistry/microbiology deficiencies
- Second Major not approvable actions
- Questions on policies/regulatory issues
- Meeting requests

Who to Call for Other Questions

- Bioequivalence Project Managers for bioequivalence issues/deficiency comments

- Labeling Team Leaders for Supplemental Applications providing only for labeling

ChemistryProject Managers: Roles and Responsibilities

- *Serves as the primary facilitator in moving applications through the approval process*

  - Interacts with all review disciplines, other OGD project managers, Office of Compliance
  - Apprises senior management of status of reviews
  - Tracks all assignments using the Master Queue

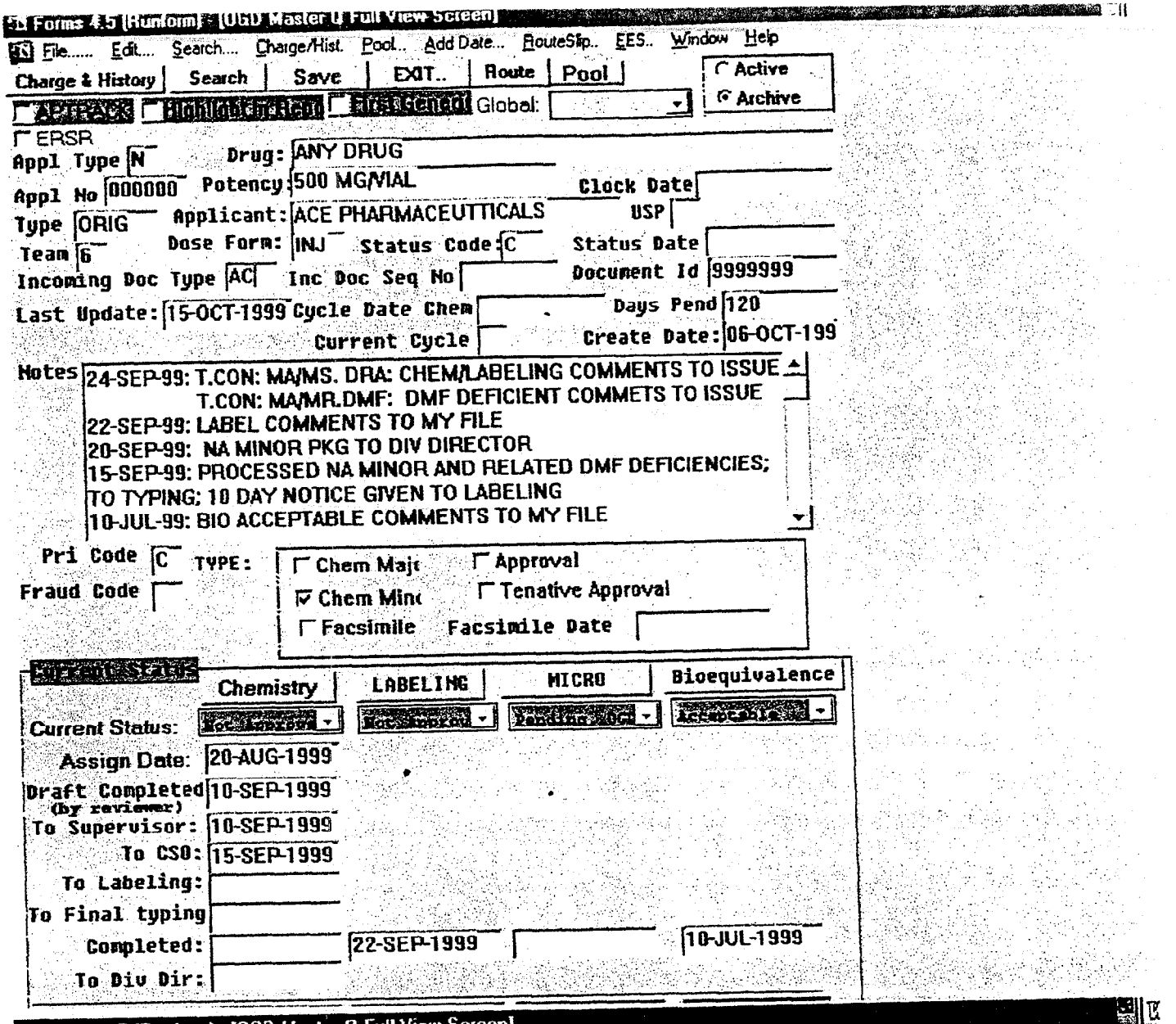
4.5 (Runform) - [Welcome OGD Master Que]

MASTERQ Delete.. Charge_History Reviewer Qs Other Workload Reports Window

.come - OGD Master Queue Tracking

The Master Queue Provides a Single Data Base to Record All Pertinent Information

- Notes on current status/processing activities
- Chem and Labeling team leaders and Micro and Bio PM entry of review status/completion dates
- Establishment evaluation report notes
- Methods validation notes
- Record of telephone conversations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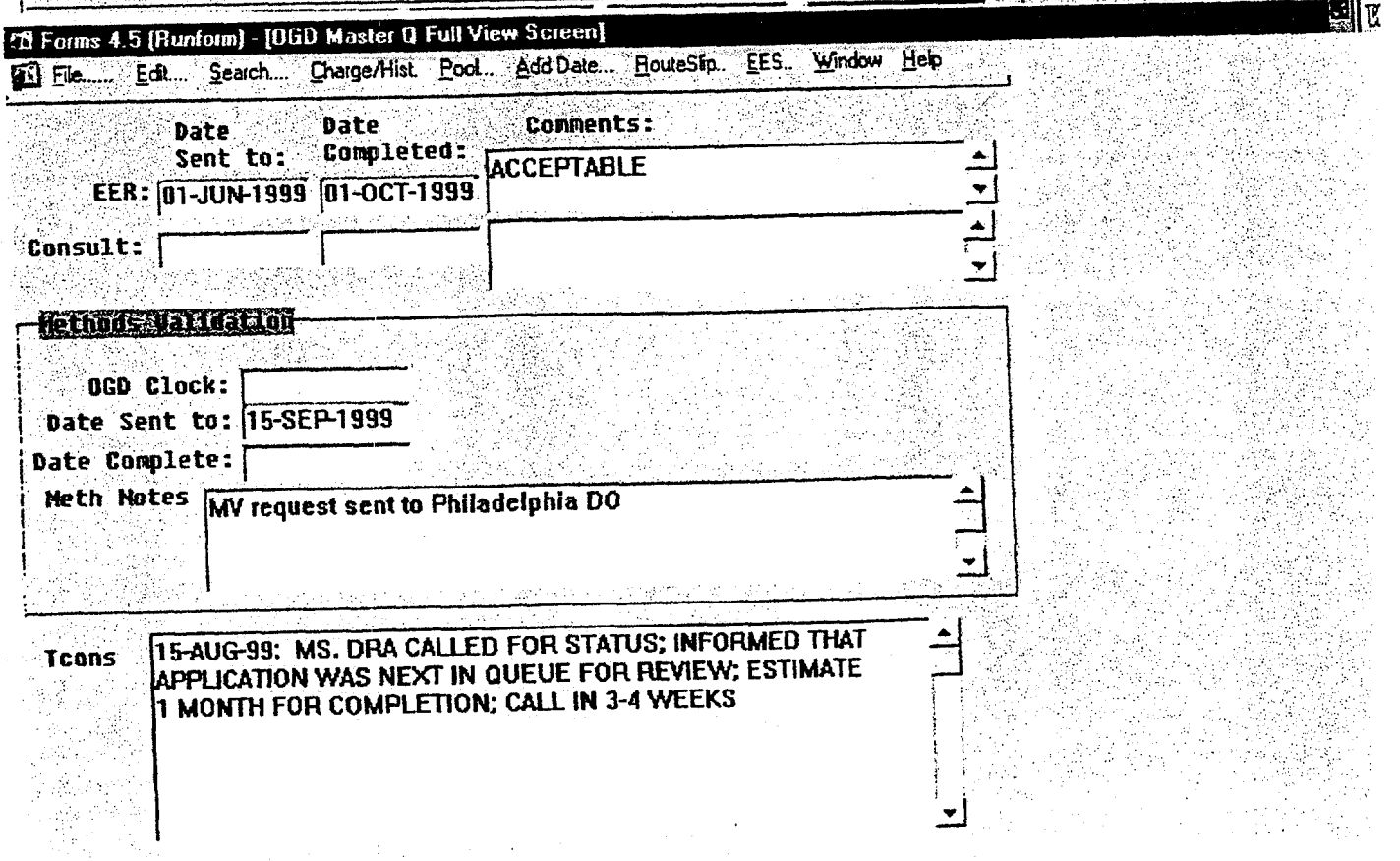
Charge & History | Search | Save | EXIT.. | Route | Pool
Active / Archive
AP Pack | Highlight Record | First Screen | Global:
ERSR
Appl Type: N Drug: ANY DRUG
Appl No: 000000 Potency: 500 MG/VIAL Clock Date:
Type: ORIG Applicant: ACE PHARMACEUTTICALS USP:
Team: 6 Dose Form: INJ Status Code: C Status Date:
Incoming Doc Type: AC Inc Doc Seq No: Document Id: 9999999
Last Update: 15-OCT-1999 Cycle Date Chem: Days Pend: 120
Current Cycle: Create Date: 06-OCT-199
Notes:
24-SEP-99: T.CON: MA/MS. DRA: CHEM/LABELING COMMENTS TO ISSUE
T.CON: MA/MR.DMF: DMF DEFICIENT COMMETS TO ISSUE
22-SEP-99: LABEL COMMENTS TO MY FILE
20-SEP-99: NA MINOR PKG TO DIV DIRECTOR
15-SEP-99: PROCESSED NA MINOR AND RELATED DMF DEFICIENCIES;
TO TYPING; 10 DAY NOTICE GIVEN TO LABELING
10-JUL-99: BIO ACCEPTABLE COMMENTS TO MY FILE
Pri Code: C TYPE:
Fraud Code:
Chem Maj Approval
Chem Min Tenative Approval
Facsimile Facsimile Date:
Current Status
Chemistry | LABELING | MICRO | Bioequivalence
Current Status: Not Reviewed | Not Required | Pending w/ OGD | Acceptable
Assign Date: 20-AUG-1999
Draft Completed (by reviewer): 10-SEP-1999
To Supervisor: 10-SEP-1999
To CSO: 15-SEP-1999
To Labeling:
To Final typing
Completed: 22-SEP-1999 10-JUL-1999
To Div Dir: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Date Sent to: | Date Completed: | Comments:
EER: 01-JUN-1999 | 01-OCT-1999 | ACCEPTABLE
Consult:
Method Validation
OGD Clock:
Date Sent to: 15-SEP-1999
Date Complete:
Meth Notes: MV request sent to Philadelphia DO
Tcons:
15-AUG-99: MS. DRA CALLED FOR STATUS; INFORMED THAT APPLICATION WAS NEXT IN QUEUE FOR REVIEW; ESTIMATE 1 MONTH FOR COMPLETION; CALL IN 3-4 WEEKS

Chemistry Project Managers: Roles and Responsibilities

- *Responsible for helping to ensure consistency in the review process*
  - consistent processing of Major, Minor, FAX and DMF deficiencies
  - alerts Document Room staff to convert FAX amendments to minor if no response within 30 days
  - Performs quality control check on incoming priority submissions to ensure completeness, accuracy

Role of the Project Manager in the Final Approval Process

- *Conducts Over-all Assessment of Approval Status*

  - Identifies incomplete reviews or necessary action items
  - Determines compliance status
  - Notifies Citizens Petition Coordinator if approval of the application may be impacted by a citizens petition
  - Represents Chemistry team at weekly approvals meeting

Role of the Project Manager in the Final Approval Process (con't)

- *Prepares Approval Letter*
  - Full vs Tentative Approval
  - Paragraph III
  - Paragraph IV
  - 180 day Generic Drug Exclusivity
  - Pediatric Exclusivity (FDAMA)
- Routes approval package for final signoffs
- Your application is approved!

Chemistry Project Managers: Roles and Responsibilities

Role of the Project Manger in Processing Supplemental Applications

- Requests inspections through EES system if necessary
- Tracks changes being effected (CBE) Supplements and notifies applicant if CBE status is denied
- Makes initial grant/deny recommendation on Expedited Review Requested Supplements and follows-up with applicant in accord with MAPP 5240.1